

Amendments to the Claims:

This listing of claims will replace all prior versions and listing of claims in the application.

1. (withdrawn) A method for delivering at least one therapeutic agent to a patient in need thereof comprising contacting patient mucosa with a formulation comprising:

- (a) a composition selected from the group consisting of synthetic cervical mucus, synthetic vaginal fluid, and both synthetic cervical mucus and synthetic vaginal fluid, and,
- (b) at least one therapeutic agent.

2. (withdrawn) The method of claim 1, wherein the mucosa is vaginal or rectal.

3. (withdrawn) The method of claim 1, wherein the patient is human and the therapeutic agent is N-[4-chloro-3-(3-methyl-2-butenyloxy)phenyl] (UC-781) or a derivative thereof.

4. (withdrawn) The method of claim 3, wherein the UC-781 is present in the formulation from at least about 0.001% to at least about 1.0% wt %.

5. (withdrawn) The method of claim 1, wherein at least one therapeutic agent is selected from the group consisting of hormones, anti-microbial agents, anti-viral agents, analgesic agents and anaesthetic agents.

Claims 6 and 7 (cancelled)

8. (withdrawn) The method of claim 1 wherein the synthetic vaginal fluid has at least two properties equal to, or substantially identical to, the properties of a composition comprising: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of about 4.2; the properties selected from the group consisting of: pH, osmolarity and surface tension.

9. (withdrawn) The method of claim 1 wherein the synthetic vaginal fluid has the following composition: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of 4.2.

10. (withdrawn) The method of claim 1, wherein the composition in step a) is synthetic cervical mucus comprising a viscosity which is optimal for delivery of at least one therapeutic agent.

11. (withdrawn) The method of claim 1, wherein the viscosity of the synthetic cervical mucus is from about 2,000 cP to about 10,000 cP.

12. (withdrawn) The method of claim 1, wherein the synthetic cervical mucus comprises guar gum present at about 1.00% w/w; and, dried gastric mucin (type III) present at about 0.50 % w/w wherein the guar gum is cross-linked with borate.

13. (withdrawn) The method of claim 12, wherein the synthetic cervical mucus further comprises imidurea, present at about 0.30 % w/w; methylparaben, present at about 0.15 % w/w; and, propylparaben, present at about 0.02 % w/w.

14. (withdrawn) The method of claim 13 wherein the synthetic cervical mucus further comprises dibasic potassium phosphate, present at about 0.26 % w/w; and, monobasic potassium phosphate, present at about 1.57% w/w.

15. (currently amended) A method for treating or preventing a disease comprising contacting mucosa of a patient in need thereof with a formulation comprising:

(a) ~~a composition selected from the group consisting of: a composition comprising synthetic cervical mucus, a composition comprising synthetic vaginal fluid suitable for vaginal use, and a composition comprising both synthetic cervical mucus and synthetic vaginal fluid,~~ and,

(b) an amount of at least one therapeutic agent effective to treat or prevent the disease.

Claims 16 to 21 (cancelled)

22. (currently amended) The method of claim 15 wherein the synthetic vaginal fluid has at least two properties equal to, or substantially identical to, the properties of a composition comprising NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of about

4.2; the properties selected from the group consisting of: pH, osmolarity and surface tension.

23. (currently amended) The method of claim 15 wherein the synthetic vaginal fluid has the following composition comprises one or more components selected from the group consisting of: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of 4.2.

Claims 24 to 28 (cancelled)

29. (withdrawn) A method for delivery of an effective amount of at least one therapeutic agent to a mucosal surface of a subject comprising administering a formulation to the mucosal surface wherein the formulation comprises guar gum present at about 1.00% w/w, dried gastric mucin (type III) present at about 0.50 % w/w and a therapeutic agent present in an amount sufficient to be effective when the formulation is administered.

Claims 30 to 37 (cancelled)

38. (withdrawn) The method of claim 29 wherein the synthetic vaginal fluid has at least two properties equal to, or substantially identical to, the properties of a composition comprising: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of about 4.2; the properties selected from the group consisting of: pH, osmolarity and surface tension.

39. (withdrawn) The method of claim 29 wherein the synthetic vaginal fluid has the following composition: NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L; wherein the composition has a pH of 4.2.

Claims 40 to 52 (cancelled)

53. (new) The method of claim 23 wherein the concentration of one or more components of the synthetic fluid is selected from the group consisting of NaCl, 3.51 g/L; KOH, 1.40 g/L; Ca(OH)₂ 0.222 g/L; serum

albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L.

54. (new) The method of claim 15 wherein the composition has a pH of 4.2.

55. (new) The method of claim 15 wherein the synthetic fluid comprises NaCl, 3.51 g/L; KOH, 1.40 g/L; $\text{Ca}(\text{OH})_2$ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L.

55. (new) The method of claim 15 wherein the synthetic fluid consists of NaCl, 3.51 g/L; KOH, 1.40 g/L; $\text{Ca}(\text{OH})_2$ 0.222 g/L; serum albumin, 0.018 g/L; lactic acid, 2.0 g/L; acetic acid, 1.0 g/L; glycerol, 0.16 g/L; urea 0.4 g/L; and glucose, 5.0 g/L.

56. (new) The method of claim 15 wherein the therapeutic agent is N-[4-chloro-3-(3-methyl-2-butenyloxy)phenyl] (UC-781) or a pharmaceutically acceptable salt thereof.

57. (new) The method of claim 15 wherein the disease is a sexually transmitted disease.

58. (new) The method of claim 57 wherein the sexually transmitted disease is transmitted by a virus.

59. (new) The method of claim 58 wherein the virus is Human Immunodeficiency Virus (HIV).

60. (new) The method of claim 15 wherein the disease is Acquired Immunodeficiency Syndrome (AIDS).